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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,985	12/21/2001	Jay M. Short	DIVER1370-8	9024
25225	7590	05/18/2005	EXAMINER	
MORRISON & FOERSTER LLP 3811 VALLEY CENTRE DRIVE SUITE 500 SAN DIEGO, CA 92130-2332			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,985

Applicant(s)

SHORT, JAY M.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-31 and 33-49 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4, 8-14 and 19-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/15/04, 9/27/02, 2/20/03, 3/4/03, 6/2/03, 2/17/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Application

Claims 8-31 and 33-49 are pending.

Applicant's election without traverse of Group I, claims 8-14 and 19-41 drawn to a food and feed comprising a phytase in a communication filed on 2/24/2005 is acknowledged.

Applicant's amendment of claims 8, 12, 13-14, 19, 24, 33, 41, addition of claims 42-49, and cancellation of claim 32 in a communication filed on 2/24/2005 is acknowledged.

New claims 42-49 are directed to the elected invention. Claims 8-14, 19-49 are under consideration and are being examined herein. Claims 15-18 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

1. The use of the trademarks has been noted in this application. See, for example, "Qiagen", "Stratagene", etc. They should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Priority

2. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/580,515 filed on 05/25/2000, 09/318,528 filed on 05/25/1999, 09/291,931 filed on 04/13/1999, 09/259,214 filed on 03/01/1999, and 08/910,798 filed on 08/13/1997.

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3. As a result of a sequence search, it has been found that SEQ ID NO: 2, as disclosed in the sequence listing, was first disclosed in U.S. Application No. 09/259,214 filed on 03/01/1999. Thus, for prior art purposes, the priority date used is 03/01/1999.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 9/20/2002, 9/27/2002, 2/20/2003, 3/4/2003, 6/2/2003, 2/17/2004, 9/15/2004 are acknowledged. Reference ADD of the IDS filed on 9/20/2002 has not been considered since it is missing the corresponding database and publication date. The remainder of the submission filed on 9/20/2002 as well as the submissions filed on 9/27/2002, 2/20/2003, 3/4/2003, 6/2/2003, 2/17/2004, 9/15/2004 are in compliance with the provisions of 37 CFR 1.97 and are being considered by the examiner.

Claim Objections

5. Claims 12 and 49 are objected to due to the recitation of "wherein the polypeptide has an amino acid sequence as set forth in: e)...; or f)...". To avoid confusion, it is suggested that the terms "e)" and "f)" not be used since "a)-d)" have been used in reference to the nucleic acid. An alternative solution could be to amend the claim to recite "wherein the polypeptide has an amino acid sequence as set forth in: 1)...; or 2)...", or "wherein the polypeptide has the amino acid sequence as set forth in SEQ ID NO: 2, or amino acids 1-432 of SEQ ID NO: 2". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 21-23, 26, 30, 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
8. Claim 21 is indefinite in the recitation of "food supplement...is fed to the animal" as lacking antecedent basis for the term "animal". While one of skill in the art would understand that the term "food supplement" in claims 19-20 refers to both animals and humans, by reciting the term "the animal" it appears as if the term "food supplement" is intended to refer to animals only, which is not the common interpretation of the term. For examination purposes, it will be assumed that the term reads "food supplement...is fed to an animal". Correction is required.
9. Claim 22 is indefinite in the recitation of "plant cell comprises a transgenic plant or plant part" for the following reasons. A plant cell is the smallest structural unit capable of independent functioning. Therefore, a plant or a plant part comprises plant cells. For examination purposes, the term will be interpreted as "plant cell is in a transgenic plant or plant part". Correction is required.
10. Claim 23 is indefinite in the recitation of "the composition comprises an aqueous liquid formulation". It is unclear if the composition is a liquid formulation or if the composition has an additional component which is a liquid formulation. For examination purposes, it will be assumed that the term reads "the composition is an aqueous liquid formulation". Correction is required.
11. Claim 26 is indefinite in the recitation of "cell lysate or equivalent" as it is unclear what is encompassed by the term "equivalent" and the specification does not provide a definition of an equivalent for a cell lysate. For examination purposes, no patentable weight will be given to the term "equivalent". Correction is required.
12. Claim 30 is indefinite in the recitation of "a *Schizosaccaromyces pombe*" since this organism is excluded from the scope of claim 29, from which the instant claim depends. For examination purposes, no patentable weight has been given to the term. Correction is required.

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13. Claim 38 is indefinite in the recitation of “nucleic acid comprises a cloning vehicle” for the following reasons. As known in the art, cloning vehicles (i.e. vectors) are large pieces of DNA which comprise a protein-encoding DNA. Therefore, it is the cloning vehicle (larger piece) which comprises the protein-encoding DNA (smaller piece). For examination purposes, it will be assumed that the claim reads “nucleic acid is contained in a cloning vehicle”. Correction is required.

14. Claim 39 is indefinite in the recitation of “wherein the cloning vehicle comprises an expression cassette, a vector, a plasmid ...” for the following reasons. As written, it is unclear if (a) the intended meaning of the term “comprises” is equivalent to “is”, (b) the cloning vehicle physically contains what is recited immediately after the term, since the term “comprises” can be understood as “has” or “contains”, or (3) the cloning vehicle can be anything else in addition to what is being recited immediately after due to the fact that the term “comprises” is considered open language. For examination purposes, it will be assumed that the term reads “wherein the cloning vehicle is....”. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 9, 26, 29-30, 34-35, 39 as presented in a preliminary amendment filed on 2/17/2004 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 9 and 26 are directed in part to a feed comprising a phytase wherein the phytase is encoded by a nucleic acid which is expressed *in vitro* in a cell lysate. Claims 29, 30, 34-35 are directed to

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a feed comprising a phytase wherein the phytase is encoded by a nucleic acid expressed in specific bacterial organisms. Claim 39 is directed in part to a feed comprising a phytase wherein the phytase is encoded by a nucleic acid which is contained in a bacteriophage. While the Examiner has been able to locate support for a feed comprising a phytase wherein said phytase is encoded by a nucleic acid which is expressed in a cell, including *E. coli*., *B. subtilis*, and *Saccharomyces cerevisiae*, the Examiner has not been able to locate support in the specification or the claims as originally filed for a feed comprising a phytase wherein said phytase is encoded by a nucleic acid which is (1) expressed *in vitro* in a cell lysate, (2) expressed in any of the specific yeast microorganisms recited in claims 29-30, with the exception of *Saccharomyces cerevisiae*, (3) expressed in any of the gram-positive bacteria recited in claims 34-35, with the exception of *Bacillus subtilis*, or (4) contained in a bacteriophage. Thus, there is no indication that the claimed feed was within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

17. Claims 8-11, 13, 19, 23-31, 33-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-11, 13, 19, 23-31, 33-40 are directed to a feed or food composition comprising a genus of phytases encoded by nucleic acids derived from any bacteria. Claims 41-48 are directed to a feed or food composition comprising a genus of phytases encoded by nucleic acids derived from *E. coli* or *E. coli* B. While the specification discloses a single *E. coli* phytase (SEQ ID NO: 2) and its corresponding cDNA (SEQ ID NO: 1), the specification is completely silent in regard to the structures of all phytases from other bacteria, other phytases from other *E. coli* strains, or other phytases found in *E. coli* B. Also,

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while the claims encompass feeds/foods comprising derivatives (i.e. variants) of any naturally-occurring phytase of bacterial origin since the term “derived” has been interpreted as encompassing any variant of any bacterial phytase, the specification is completely silent in regard to the structural elements required in any variant of any bacterial phytase such that it will display phytase activity, nor has the specification provided any clue as to the structural elements required in any variant of the polypeptide of SEQ ID NO: 2 required to display phytase activity. Furthermore, the specification fails to disclose the structural elements in the polypeptide of SEQ ID NO: 2 which are associated with any phytase from *E. coli* or *E. coli* B.

The genus of phytases required in the claimed feed/food compositions is an extremely large and structurally variable genus. While a sufficient written description of a genus of polypeptides may be achieved by a recitation of a representative number of polypeptides defined by their amino acid sequence or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus., in the instant case, there is no structural feature which is representative of all the members of the genus of phytases recited in the claims. Furthermore, while one could argue that the recited genus of polypeptides is adequately described by the polypeptide of SEQ ID NO: 2, since one could apply structural homology using the structure of SEQ ID NO: 2 and those known in the art to isolate other phytases as required by the claimed feed/food compositions, it is noted that the art teaches the unpredictability of using structural homology to accurately determine function and even a high degree of structural homology may not result in functional homology. Witkowski et al. (Biochemistry 38:11643-11650, 1999; cited in the IDS) teaches that one amino acid substitution transforms a β -ketoacyl synthase into a malonyl decarboxylase and completely eliminates β -ketoacyl synthase activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001; cited in the IDS) teaches that two naturally occurring *Pseudomonas* enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and dehalogenation, therefore having different function. Therefore, in the absence

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of any additional information correlating structure with phytase activity, or any correlation between SEQ ID NO: 2 and phytase activity, many structurally unrelated polypeptides are encompassed by the genus. The specification only discloses a single species of the genus, i.e. SEQ ID NO: 2, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus of polypeptides required to practice the claimed method. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

18. Claims 8-11, 13, 19, 23-31, 33-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a feed/food composition comprising the phytase of SEQ ID NO: 2, does not reasonably provide enablement for a feed/food composition comprising any bacterial phytase or any derivative of a bacterial phytase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

The scope of the claims, as discussed above, is not commensurate with the enablement provided in view of the large number of undisclosed bacterial phytases, and derivatives thereof, required to practice the claimed invention. While the phytase of SEQ ID NO: 2 has been disclosed, there is no disclosure of (1) the structure of all the other bacterial phytases, or derivatives thereof, required to make the claimed compositions, (2) structural features common to all bacterial phytases, (3) critical structural

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elements in any bacterial phytase or the polypeptide of SEQ ID NO: 2 which are required in any polypeptide to display phytase activity, or (4) the structural elements in the polypeptide of SEQ ID NO: 2 which are required in any *E. coli* or *E. coli B* phytase. The art as discussed above, teaches the unpredictability of isolating proteins of similar function based solely on structural homology and indicates that even highly structurally homologous proteins do not necessarily share the same function. Since structure determines function, one of skill in the art would require some knowledge or guidance as to which are the structural elements in a bacterial protein which are required for phytase activity. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to display the desired function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those bacterial polypeptides having phytase activity, or the structural elements which can be modified in those bacterial phytases such that variants of said bacterial phytases would also display phytase activity to practice the full scope of the claimed invention. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 8-13, 19, 23, 26-31, 33-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Apajalahti et al. (GB 2316082 A, published 2/18/1998).

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Claims 8-13, 19, 26-31, 33-40 of the instant application are directed in part to a feed/food composition comprising a bacterial phytase wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how the bacterial phytase is made does not affect the structure or function of the phytase, no consideration has been placed on limitations regarding the method of making the phytase. Claim 23 is directed in part to a food composition comprising a bacterial phytase wherein said composition comprises a liquid formulation.

Apajalahti et al. teaches a food and feed composition comprising a *B. subtilis* phytase (page 10). Furthermore, Apajalahti et al. teaches that the phytase can be added to the food/feed composition in liquid form (page 10). Apajalahti et al. teaches the isolation of the *B. subtilis* phytase, its amino acid sequence (SEQ ID NO: 2), the corresponding cDNA and its nucleic acid sequence (SEQ ID NO: 1). Apajalahti et al. teaches production of the recombinant phytase in *E. coli* (Example 3), vectors comprising the nucleic acid used for expression of the phytase (Example 3), secretion of the phytase via a signal peptide (page 9, lines 3-10), recombinant production of the phytase in prokaryotic and eukaryotic host cells including yeast cells, bacterial cells, plant cells, fungal cells, *Saccharomyces* cells, *Pichia* cells, gram-positive cells, gram-negative cells, *E. coli* cells, *Bacillus subtilis* cells, *Lactobacillus* cells, *Lactococcus* cells, and *Aspergillus* cells (page 9, lines 11-28). Therefore, the teachings of Apajalahti et al. anticipate the instant claims as written.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claims 8-13, 19, 23-24, 26-31, 33-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS).

Claims 8-13, 19, 26-31, 33-40 of the instant application are directed in part to a feed/food composition comprising a bacterial phytase wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how the bacterial phytase is made does not affect the structure or function of the phytase, no consideration has been placed on limitations regarding the method of making the phytase. Claim 23 is directed in part to the food composition of claim 19 wherein the composition comprises a liquid formulation. Claim 24 is directed to a drinkable foodstuff comprising a recombinant bacterial phytase.

Cheng et al. teaches a feed composition (column 2, lines 60-61), food compositions for humans (column 13, lines 2-3), liquid formulations (column 12, lines 32-40), and drinking water with a *Selenomonas ruminantium* phytase (column 12, lines 37-38). Cheng et al. teaches the isolation of the *Selenomonas ruminantium* phytase, its amino acid sequence (SEQ ID NO: 2), the corresponding cDNA and its nucleic acid sequence (SEQ ID NO: 1). Cheng et al. teaches production of the recombinant phytase in *E. coli* (gram-negative bacterial cell; Example 7), *Pichia pastoris* (eukaryotic fungal cell; Example 7), *B. napus* (plant cell; Example 7), vectors comprising the nucleic acid used for expression of the phytase (Example 7, columns 18-21), secretion of the phytase via a signal peptide (Example 7, column 19, lines 55-67; column 8, lines 51-57; column 9, lines 32-47), recombinant production of the phytase in *Saccharomyces cerevisiae* cells (yeast cells; column 8, lines 40-45), *Bacillus subtilis* cells (gram-positive bacterial cells; column 8, lines 40-45), and *Aspergillus ficuum* cells (column 8, lines 40-45). Therefore, the teachings of Cheng et al. anticipate the instant claims as written.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill

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in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). The teachings of Cheng et al. have been described above. Cheng et al. does not teach a drinkable foodstuff comprising juice and the phytase. Claim 25 is directed in part to the drinkable foodstuff of claim 24 wherein the foodstuff further comprises juice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add juice to the drinkable water phytase composition of Cheng et al. A person of ordinary skill in the art is motivated to add juice to add flavor and possibly some sweetness to the drinking water of Cheng et al. so that the phytase composition is more palatable. One of ordinary skill in the art has a reasonable expectation of success at adding juice to the drinking water of Cheng et al. since this is an extremely common and easy to do step. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

24. Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apajalahti et al. (GB 2316082 A, published 2/18/1998) in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). The teachings of Cheng et al. and Apajalahti et al. have

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been described above. Apajalahti et al. does not teach a drinkable foodstuff comprising the phytase or juice comprising the phytase. Cheng et al. does not teach a drinkable foodstuff comprising juice and the phytase. Claim 24 is directed to a drinkable foodstuff comprising a bacterial phytase. Claim 25 is directed in part to the drinkable foodstuff of claim 24 wherein the foodstuff further comprises juice.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the phytase of Apajalahti et al. to drinkable water, as taught by Cheng et al. or to add juice to drinkable water comprising the phytase. A person of ordinary skill in the art is motivated to add the phytase of Apajalahti et al. to drinkable water to provide an additional delivery method which can be used in case the target subject may not be able to chew. Also, a person of ordinary skill in the art is motivated to add juice to add flavor and possibly some sweetness to drinking water comprising the phytase of Apajalahti so that the phytase composition is more palatable. One of ordinary skill in the art has a reasonable expectation of success at adding the phytase to drinking water or add juice to drinking water since this is an extremely common and easy to do step. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

25. Claims 42-43, 45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS). The teachings of Cheng et al. have been discussed above. Cheng et al. does not teach an *E. coli* phytase. Greiner et al. teaches two *E. coli* phytases (Abstract; page 10, right column, Results, Purification of the phytases) and teaches that phytases are of special interest in biotechnological applications specially for the reduction of phytate in feedstuff and food (page 107, right column, last paragraph of Introduction). Greiner et al. does not teach the feed/food compositions of Cheng et al.

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Claims 42-43, 45 and 47 are directed in part to the feed/food compositions of claims 8, 13 and 19 wherein the phytase is from *E. coli*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a feed/food composition, as taught by Cheng et al. with the phytases of Greiner et al. A person of ordinary skill in the art is motivated to make the feed/food compositions with the *E. coli* phytases of Greiner et al. because Greiner et al. teaches that phytases are of great interest specially for the reduction of phytate in food and feedstuff. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the *E. coli* phytases since all that is required is replacing the phytases of Cheng et al. with those of Greiner et al. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

26. Claims 42-43, 45, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apajalahti et al. (GB 2316082 A, published 2/18/1998) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS). The teachings of Apajalahti et al. have been discussed above. Apajalahti et al. does not teach an *E. coli* phytase. Greiner et al. teaches two *E. coli* phytases (Abstract; page 10, right column, Results, Purification of the phytases) and teaches that phytases are of special interest in biotechnological applications specially for the reduction of phytate in feedstuff and food (page 107, right column, last paragraph of Introduction). Greiner et al. does not teach the feed/food compositions of Apajalahti et al.

Claims 42-43, 45 and 47 are directed in part to the feed/food compositions of claims 8, 13 and 19 wherein the phytase is from *E. coli*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a feed/food composition, as taught by Apajalahti et al. with the phytases of Greiner et al. A person of ordinary skill in the art is motivated to make the feed/food compositions with the *E. coli*

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phytases of Greiner et al. because Greiner et al. teaches that phytases are of great interest specially for the reduction of phytate in food and feedstuff. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the *E. coli* phytases since all that is required is replacing the phytases of Apajalahti et al. with those of Greiner et al. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Double Patenting

27. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

28. Claims 8-14, 19-20, 23, 26-31, 33-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s).

See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

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Claims 6-7 of U.S. Patent No. 6110719 are directed to an animal feed composition comprising a microbial phytase comprising the sequence set forth in SEQ ID NO: 2. The phytase of claims 6-7 of U.S. Patent No. 6110719 has been disclosed as being isolated from *E. coli* B. Claims 8-14, 19-20, 26-31, 33-46 of the instant application are directed in part to a feed/food composition comprising the *E. coli* B phytase of SEQ ID NO: 2, wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how it is made does not affect the structure or function of the phytase of SEQ ID NO: 2, no consideration has been placed on limitations regarding the method of making the phytase. Therefore, the feed composition of claims 6-7 of U.S. Patent No. 6110719 anticipate the instant claims as written. Claim 23 of the instant application is directed to the food composition of claim 19 wherein the composition comprises a liquid formulation. It would have been obvious to one of skill in the art to add a liquid to the feed composition of claims 6-7 of U.S. Patent No. 6110719 to decrease its viscosity and make the feed composition easier to eat. One of ordinary skill in the art has a reasonable expectation of success at adding liquids to the feed of claims 6-7 of U.S. Patent No. 6110719 since this is an extremely easy step. Therefore, the invention of claim 23 of the instant application as a whole would have been prima facie obvious over claims 6-7 of U.S. Patent No. 6110719 to a person of ordinary skill in the art at the time the invention was made.

29. Claims 21-22, 24-25, 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-7 of U.S. Patent No. 6110719 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010

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(Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 6-7 of U.S. Patent No. 6110719 are directed to an animal feed composition comprising a microbial phytase comprising the sequence set forth in SEQ ID NO: 2. The teachings of Cheng et al. have been discussed above. Cheng et al. also teaches a feed composition comprising the phytase in plants (column 12, lines 8-12). Claims 21-22 of the instant application are directed in part to a food composition comprising the phytase of SEQ ID NO: 2 wherein the nucleic acid encoding the phytase is expressed in a plant cell comprised in a transgenic plant wherein the plant cell is fed to an animal. Claims 24-25 and 47-49 are directed in part to a drinkable foodstuff comprising the phytase of SEQ ID NO: 2 wherein the drinkable foodstuff contains juice. It would have been obvious to one of skill in the art at the time the invention was made to make a food composition or drinkable water, as taught by Cheng et al. with the phytase used in the compositions of claims 6-7 of U.S. Patent No. 6110719. A person of ordinary skill in the art is motivated to make the food compositions with the phytase used in the composition of claims 6-7 of U.S. Patent No. 6110719 because providing the transgenic plant directly to an animal would save time and money as no purification of the phytase would be required. Also, a person of ordinary skill in the art is motivated to add the phytase used in the composition of claims 6-7 of U.S. Patent No. 6110719 to drinkable water or add juice to drinkable water since Cheng et al. teaches that phytases can also be useful in food compositions for humans, and providing such phytase composition in water or juice would provide an alternative method of delivering the phytase to a human which may not be able to chew. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the phytase used in the composition of claims 6-7 of U.S. Patent No. 6110719 since all that is required is replacing the phytase of Cheng et al. with that of claims 6-7 of U.S. Patent No. 6110719. Therefore, the invention of claims 21-22, 24-25 and 47-49 of the instant application

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as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

30. Claims 8-14, 19-31, 33-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 23-28, 30-31, 40-49 of copending Application No. 10/601319. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. Claims 8-14, 19-20, 26-31, 33-46 of the instant application are directed in part to a feed/food composition comprising the *E. coli* B phytase of SEQ ID NO: 2, wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Claim 23 of the instant application is directed to the food composition of claim 19 wherein the composition comprises a liquid formulation. Claims 21-22 of the instant application are directed in part to a food composition comprising the phytase of SEQ ID NO: 2 wherein the nucleic acid encoding the phytase is expressed in a plant cell comprised in a transgenic plant wherein the plant cell is fed to an animal. Claims 24-25 and 47-49 of the instant application are directed in part to a drinkable foodstuff comprising the phytase of SEQ ID NO: 2 wherein the drinkable foodstuff contains liquor, wine, a mixed alcoholic drink, a wine cooler, an alcoholic coffee, a beer, a near-beer, an extract, a homogenate or a puree. Claims 5, 23-28, 30-31, 40-49 of copending Application No. 10/601319 are directed to a feed/food composition or a drinkable foodstuff wherein said feed/food composition or foodstuff comprise the phytase of SEQ ID NO: 2, wherein the foodstuff comprises liquor, wine, a mixed

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alcoholic drink, a wine cooler, an alcoholic coffee, a beer, a near-beer, an extract, a homogenate or a puree, and wherein the phytase in the food composition is contained in a plant cell fed which is fed to an animal. Therefore claims 5, 23-28, 30-31, 40-49 of copending Application No. 10/601319 anticipate the instant claims as written.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

31. Claims 8-14, 19-20, 23, 24, 26-31, 33-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/933115. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 8-14, 19-20, 26-31, 33-46 of the instant application are directed in part to a feed/food composition comprising the *E. coli* B phytase of SEQ ID NO: 2, wherein the phytase is made by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how the phytase is made does not affect the structure or function of the phytase of SEQ ID NO: 2, no consideration has been placed on limitations regarding the method of making the phytase. Claim 23 of the instant application is directed to the food composition of claim 19 wherein the composition comprises a liquid formulation. Claims 24 and 47-49 of the instant application are directed in part to a drinkable foodstuff comprising the phytase of SEQ ID NO: 2. Claims 1, 3-14 of copending

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Application No. 10/933115 are directed in part to a formulation comprising the phytase of SEQ ID NO:

2. Claim 2 of copending Application No. 10/933115 is directed to the formulation of claim 1 wherein the formulation is a dietary supplement. Claim 15 is directed to the formulation of claim 1 wherein the formulation comprises a drink. Since a preferred embodiment of copending Application No. 10/933115 is a formulation which is a dietary supplement for animals and humans, also in liquid form, the formulation of claims 1-15 of copending Application No. 10/933115 is an obvious variation of the feed/food compositions of claims 8-14, 19-20, 23, 24, 26-31, 33-49 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

32. Claims 8-14, 19-20, 23, 26-31, 33-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88-89, 96-103 of copending Application No. 11/056354. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 88-89, 96-103 of copending Application No. 11/056354 are directed to a feed/food composition comprising a microbial phytase comprising the sequence set forth in SEQ ID NO: 2. The phytase of claims 88-89, 96-103 of copending Application No. 11/056354 has been disclosed as being isolated from *E. coli* B. Claims 8-14, 19-20, 26-31, 33-46 of the instant application are directed in part to a feed/food composition comprising the *E. coli* B phytase of SEQ ID NO: 2, wherein the phytase is made

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by recombinant methods using a variety of host cells, cloning vehicles, and wherein the phytase is secreted by the cell. Since how it is made does not affect the structure or function of the phytase of SEQ ID NO: 2, no consideration has been placed on limitations regarding the method of making the phytase. Therefore, the feed composition of claims 88-89, 96-103 of copending Application No. 11/056354 anticipate the instant claims as written. Claim 23 of the instant application is directed to the food composition of claim 19 wherein the composition comprises a liquid formulation. It would have been obvious to one of skill in the art to add a liquid to the feed/food composition of claims 88-89, 96-103 of copending Application No. 11/056354 to decrease its viscosity and make the feed/food composition easier to eat. One of ordinary skill in the art has a reasonable expectation of success at adding liquids to the feed/food composition of claims 88-89, 96-103 of copending Application No. 11/056354 since this is an extremely easy step. Therefore, the invention of claim 23 of the instant application as a whole would have been prima facie obvious over claims 88-89, 96-103 of copending Application No. 11/056354 to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

33. Claims 21-22, 24-25, 47-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 88-89, 96-103 of copending Application No. 11/056354 in view of Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645

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(Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 88-89, 96-103 of copending Application No. 11/056354 are directed to a feed/food composition comprising a microbial phytase comprising the sequence set forth in SEQ ID NO: 2. The teachings of Cheng et al. have been discussed above. Cheng et al. also teaches a feed composition comprising the phytase in plants (column 12, lines 8-12). Claims 21-22 of the instant application are directed in part to a food composition comprising the phytase of SEQ ID NO: 2 wherein the nucleic acid encoding the phytase is expressed in a plant cell comprised in a transgenic plant wherein the plant cell is fed to an animal. Claims 24-25 and 47-49 are directed in part to a drinkable foodstuff comprising the phytase of SEQ ID NO: 2 wherein the drinkable foodstuff contains juice. It would have been obvious to one of skill in the art at the time the invention was made to make a food composition or drinkable water, as taught by Cheng et al. with the phytase used in the composition of claims 88-89, 96-103 of copending Application No. 11/056354. A person of ordinary skill in the art is motivated to make the food compositions with the phytase used in the composition of claims 88-89, 96-103 of copending Application No. 11/056354 because providing the transgenic plant directly to an animal would save time and money as no purification of the phytase would be required. Also, a person of ordinary skill in the art is motivated to add the phytase used in the compositions of claims 88-89, 96-103 of copending Application No. 11/056354 to drinkable water or add juice to drinkable water since Cheng et al. teaches that phytases can also be useful in food compositions for humans, and providing such phytase composition in water or juice would provide an alternative method of delivering the phytase to a human which may not be able to chew. One of ordinary skill in the art has a reasonable expectation of success at making the feed/food compositions with the phytase used in the composition of claims 88-89, 96-103 of copending Application No. 11/056354 since all that is required is replacing the phytase of Cheng et al. with that of claims 88-89, 96-103 of copending Application No. 11/056354. Therefore, the invention of claims 21-22, 24-25 and

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47-49 of the instant application as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

34. No claim is in condition for allowance.

35. The cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

36. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

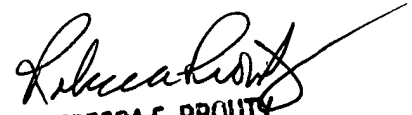
37. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 12, 2005


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800-
1600